

## ***Imaging as a Biomarker: Standards for Change Measurements in Therapy***

Breakout Area 6: Data Archival & Access Methods:  
Image, Related Meta-data and Clinical Outcome Data,  
Related Data Interoperability Standards, and Innovative  
Methodologies for Data Interpretation

Day 1: Summary of “Big Picture Roadmapping  
– The What by When?”  
Near, Mid and Long-Term Issues

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## Breakout Area 6: Data Archival & Access Methods

### Near-Term 1-3 Years

1. *State Innovation or Challenge: 21CFR11 compliant image database with audit trail (e.g., RT objects)*
  - ☐ Impact of Success: FDA will accept; can meet regulatory requirements
  - ☐ Technical Barriers: DICOM doesn't have audit trail; unwelcome burden for PACS system; content management
  - ☐ Key Players: DICOM, pharma, CRO
2. *State Innovation or Challenge: Need research PACS, but most have clinical PACS*
  - ☐ Impact of Success: Enables and facilitates clinical trial use of images
  - ☐ Technical Barriers: PACS systems are closed; vendors are not motivated to provide flexible integration of clinical trials data
  - ☐ Key Players: PACS, RIS and HIS developers; PACS customers
3. *State Innovation or Challenge: Legacy PACS = huge installed base, not suitable for research (has some, but not all necessary data; workflow is not optimal for clinical research)*
  - ☐ Impact of Success: Allows innovative use of images; clinical trials
  - ☐ Technical Barriers: Economics unfavorable; benefits difficult to quantify; add-on or add-in
  - ☐ Key Players: PACS vendors; clinical trialists, healthcare IT

## Breakout Area 6: Data Archival & Access Methods

### Near-Term 1-3 Years

4. *State Innovation or Challenge: DICOM and ISO 11179 metadata; CDISC integration of images*
  - ☐ Impact of Success: Use generic tools to handle image + other biomedical data
  - ☐ Technical Barriers: caBIG is ISO 11179 compliant, but cancer is pathology driven
  - ☐ Key Players: DICOM, NCI, CRO; CDISC
5. *State Innovation or Challenge: Capture image-guided treatment plans*
  - ☐ Impact of Success: reuse plans; quality control across centers (e.g., rf ablation)
  - ☐ Technical Barriers: target and day-to-day changes in morphology not defined; borrow on experience of ATC
  - ☐ Key Players: DICOM, ATC, NCI, interventional companies and radiologists
6. *State Innovation or Challenge: PET, MRI, neuropsych, genetic data over time on same individuals; Establish imaging as a surrogate marker for clinical outcomes*
  - ☐ Impact of Success: Validation of imaging biomarkers
  - ☐ Technical Barriers: Need to integrate multitemporal datasets on individuals linked to outcomes
  - ☐ Key Players: ADNI; OAI; RIDER

Breakout Area 6: Data Archival & Access Methods  
**Short-Term 1-3 Years**

**7. *State Innovation or Challenge: Discovery database; data mining of human clinical trial image collections; enterprise archive***

- ☐ Impact of Success: better ability for drug development
- ☐ Technical Barriers: incompatible data in local, private databases; proprietary code in tools;
- ☐ Key Players: pharma, CRO, clinical sites; IT vendors

## Breakout Area 6: Data Archival & Access Methods

### Mid-Term 3-5 Years

1. *State Innovation or Challenge: Know effects of oncology treatment over time and link to outcomes; flexible ability to add modalities and ancillary data*
  - ☐ Impact of Success: Able to sort out treatment effects from other sources of variation
  - ☐ Technical Barriers: Difficult to integrate new datasets, modality
  - ☐ Key Players: NCI, Rad Onc, Oncologists, Radiology, FDA
2. *State Innovation or Challenge: Linking disparate data in various systems; Query mechanism for multiple databases*
  - ☐ Impact of Success: allows interoperation of distributed systems, legacy and newer databases
  - ☐ Technical Barriers:
  - ☐ Key Players: database experts;

## Breakout Area 6: Data Archival & Access Methods

### Long-Term 5+ Years

1. *State Innovation or Challenge: Integrate images and receptor ligand maps*

- ❑ Impact of Success: Targeted drug therapies
- ❑ Technical Barriers: Multimodality multitemporal data management and analysis
- ❑ Key Players: Pharma; SNM – PET; ISMRM;

2. *State Innovation or Challenge: Federated integrated data base, like caBIG (has no audit trail) can't be used for drug regulatory or non-cancer applications*

- ❑ Impact of Success: Support drug development and reuse of previously collected data
- ❑ Technical Barriers: NCI-based initiative of limited value to pharma, limited involvement in design
- ❑ Key Players: NCI, pharma; healthcare IT